Inquiring Minds

News and notes from the Department of Clinical Investigation
Walter Reed Army Medical Center
Washington, D.C.

January 2003

The 29th Annual Bailey K. Ashford Research Award

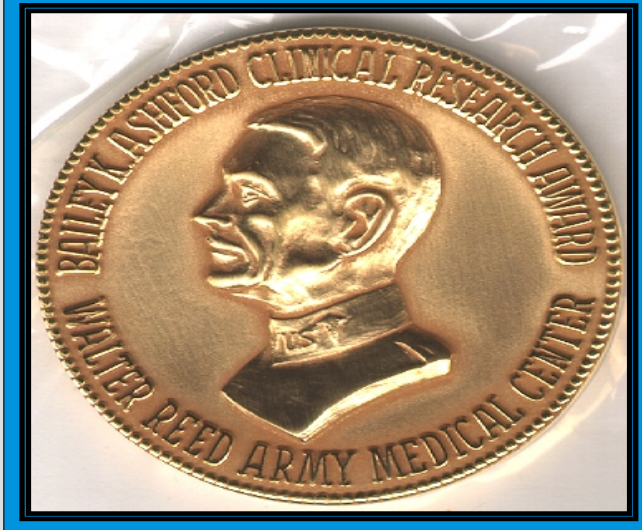
The Department of Clinical Investigation, Walter Reed Army Medical Center, is proud to announce the 29th Annual Bailey K. Ashford Clinical & Laboratory Research Award and Symposium. This year the symposium will be held on 1 May 2003 at 1300 hours in Joel Auditorium.

The BKA award is presented annually to the graduating trainee who has contributed the most significant research during his/her years of training at WRAMC. An award for clinical research, as well as laboratory research, will be made.

Application packets will be available beginning mid-January and can be downloaded from the DCI website. Any attending staff member assigned to WRAMC or to an integrated GME program may submit nominations. A selection committee determines the award finalists, who are then invited to present their major research findings at the symposium.

An engraved medallion, certificate, and monetary prize are presented to the awardees at the joint NNMC and WRAMC graduation exercise in June. A poster session will be included as part of the symposium, with an award being presented for the best poster presentation.

This award is named in honor of Colonel Bailey K. Ashford for his work in solving the problem of hookworm induced anemia in Puerto Rico during the early 1900s.



BKA Symposium: 1 May

Please contact CPT Ken Capps at (202)782-7823 if you are interested in knowing more about this award or the upcoming symposium.

CITI Web-Based Continuing Education Research Course Reminder

DCI would like to remind WRAMC researchers that completion of the Collaborative IRB Training Initiative (CITI) Continuing Education Course is required for all PIs that have not completed one of the two basic training requirements in the past 3 years.

DCI currently has two training options available to WRAMC investigators: the full length (or "core") CITI Web-based Research Course and the onsite "live" Research Course. Completion of ONE of these courses is required for all individuals wishing to serve as a Principal Investigator (PI) on a WRAMC research protocol and is highly encouraged for all personnel involved in research.

Please note that new protocols received by DCI with PIs that have not complied with this requirement may have their approval date delayed until this requirement is met. Previously trained investigators with ongoing protocols who have not been trained in the last three years need to complete this continuing education course to remain in good administrative standing.

For more information on the CITI continuing education course and to begin training see www.wramc.amedd.army.mil/Departments/dci/WebCourse-CE.htm.

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Don't Forget to Clear Your Publications!!

DCI would like to remind WRAMC personnel that all WRITTEN publications including abstracts, manuscripts, case reports, and book chapters reflecting the WRAMC affiliation must be cleared through the Public Affairs Office and the Department of Clinical Investigation. Proper clearance must be obtained before the publication is submitted for publication in a journal, book, etc.

To obtain publication clearance, complete the publication clearance form (pub-clear.doc) found on the DCI website under "Download PROTOCOL Templates." Attach a copy of your publication and have your service & department chief review & sign/date. It is then forwarded to the Public Affairs Office (Bldg 1) for review and approval. PAO will then forward to DCI.

For research related publications, DCI will verify that the research has received the appropriate institutional approval (specific information should be included for research related publications; see *pub-clear-guidelines.doc* on the DCI website). Additional approval by the Directorate of Telemedicine may be required for Web publications.

Once the publication has been reviewed and approved by DCI, the approved publication form will be faxed to the requester. This clearance form should be kept on file. DCI keeps a master database of all publication clearances processed.

For more information on publication clearance, contact CPT Ken Capps at (202) 782-7823 or via e-Mail at Ken.Capps@NA.amedd.army.mil.

WRAMC October Research Course

DCI presented the WRAMC Research Course on 17 October 2002 in Sanford Auditorium at the Uniformed Services University of the Health Sciences (USUHS) in Bethesda, MD. 122 current and potential investigators attended this one-day course.

The objective of this course is to educate WRAMC medical personnel on the ethical issues, current regulations, and design considerations in conducting medical research. Completion of this course is required for Research Coordinators and all individuals wishing to serve as a Principal Investigator (PI) on a WRAMC research protocol. The course is also encouraged for all personnel involved in research including associate investigators, data analysts, etc.

The first speaker was LTC Raul Marin, Assistant Chief of DCI, who gave participants a general overview of DCI and the resources available to investigators. Following a movie entitled: "Evolving Concern-Protection for Human Subjects," was DCI's Corrine Maydonovitch. Ms. Maydonovitch presented the attendees with step-by-step instructions on the submission and review of protocols. Next, LTC Christina Yuan provided attendees with risks and benefits of obtaining informed consent. The morning session ended with LTC Marin and Ms. Robin Howard addressing study designs and sample sizing.

After a lunch break, the program continued with Dr. Eric Marks on tissue banking, followed by Dr. Dale Vander Hamm, formerly of the Human Use Review and Regulatory Affairs office in Ft. Detrick, who spoke on the current application of human subject protection regulations. The last two speakers for the day were Mr. Stephen E. Maleson, attorney/advisor for the U.S. Army Medical Research and Materiel Command, and COL Charles Bolan of WRAIR. They addressed scientific misconduct and publication issues, respectively.

For more information on the Research Course and future dates, see the DCI website or call DCI at 782-6389.

15th Annual Tri-Service CI Scheduled for 5-7 May 2003

The 15th Annual Tri-Service Clinical Investigation Short Course is scheduled for 5-7 May 2003. This annual conference is held in San Antonio, Texas and is sponsored by the U.S. Army Clinical Investigation Regulatory Office (CIRO). This course serves as a venue for educating researchers and administrators responsible for overseeing and ensuring the ethical treatment of human research subjects enrolled in clinical research studies sponsored by the U.S. Army, Navy, and Air Force. For more information, please contact CIRO at (210)221-2511 or DSN: 471-2511.

A Multidisciplinary Program for Achieving Lipid Goals in Chronic Hemodialysis Patients*

In this section of the newsletter, DCI randomly picks a WRAMC department/service and profiles a recent article of interest by that department/service. This article profiles a joint venture by the Department of Pharmacy, Nephrology Service & Nutrition Service.

Patients on dialysis have both a high incidence of coronary artery disease (CAD) and increased CAD-related mortality relative to the general population. High low-density lipoprotein (LDL) levels have been identified as risk factors for patients on chronic dialysis. National Cholesterol Education Program (NCEP) guidelines recommend a target LDL cholesterol of 100 mg/dl in high-risk groups, however, most dialysis patients in the United States do not meet this goal. Nonetheless, there is little information on how target lipid levels can be achieved in end stage renal disease (ESRD) patients.

Researchers at Walter Reed Army Medical Center from a multidisciplinary team of pharmacists, dietitians, and nephrologists are addressing this issue. Studies have shown that the 3-hydroxy-3methylglutaryl coenzyme A (HMG-CoA) reductase inhibitors (statins) have been linked with decreased mortality in dialysis patients. While a team approach is more effective for lipid lowering, there are no published reports on using this approach in a dialysis population.

To test the effectiveness of a multidisciplinary lipid management program, WRAMC researchers retrospectively reviewed a pharmacist-directed hyperlipidemia management program for chronic hemodialysis (HD) patients. All 26 adult patients on chronic HD at WRAMC were entered into the program. A clinical pharmacist was responsible for laboratory monitoring, patient counseling, and the initiation and dosage adjustment of an appropriate HMG-CoA statin using a dosing algorithm and monitoring guidelines. A renal dietitian provided nutrition counseling and the nephrologist was notified of potential or existing drug interactions or adverse drug reactions (ADRs). Data was collected at program initiation and for 6 months thereafter.

After 6 months, 23 of 26 patients (88%) had reached target LDL cholesterol, compared with 15 patients (58%) at the start of the program. Mean LDL cholesterol decreased from 96 5 to 80 3 mg/dl, and mean total cholesterol decreased from 170 7 to 151 4 mg/dl. Fifteen adjustments in drug therapy were made with eight adverse drug reactions identified in 7 patients. Two of those required drug discontinuation or an alternative agent. Physicians were alerted to 8 potential drug- interactions, however, none resulted in an adverse event or discontinuation of therapy.

This study illustrates that improved LDL cholesterol control can be achieved in chronic HD patients using a multidisciplinary pharmacist-directed lipid program. Both feasibility and efficacy of a multidisciplinary approach were demonstrated in management of hyperlipidemia in HD patients. Overall, the program was well accepted by nurses, nephrologists and patients, with side effects minimal and several potential drug interactions avoided.

The researchers do note there are limitations to their study that include the small number of patients and lack of a control group.

Clinical pharmacist, Rebecca A. Viola, PharmD noted, “I believe the results of the study are important because it alerts physician providers to another alternative of how clinical goals can be achieved in hemodialysis patients using the skills of a variety of disciplines, including clinical pharmacist & dietitian, in addition to physician. Cholesterol management is a goal that is well suited for this type of approach, and with anticipated physician shortages, non-physician providers such as pharmacists can take a more active role.”

Dr. Viola also added, “We hope that physicians in the nephrology community as well as other specialties will continue to be open to this type of approach to disease state management.”

*Viola RA, Abbott KC, Welch PG, McMillan RJ, Sheikh AM, Yuan CM. **A multidisciplinary program for achieving lipid goals in chronic hemodialysis patients.** *BMC Nephrol. 2002 Nov 14;3(1):9.*

DCI is SHARPP..

Striving to

Help

All

Researchers from

Planning to

Publication

Step-By-Step Guide for Consenting Subjects

Congratulations! Your research study has been approved and you're probably eager to enroll subjects. The following information is intended to provide guidance on completing the WRAMC Informed Consent document (DA Form 5303-R). A sample consent form (consentform.doc) can be downloaded from the DCI website for reference.

Informed consent for research is a process that involves a dialogue between a potential research participant and the Principal Investigator (PI) or a knowledgeable designee. This dialogue consists of an explanation of the study, potential risks and benefits, confidentiality and security of data and/or specimens, compensation, steps taken to protect the participant from risk/harm, and the participant's legal rights. The consent form serves as documentation that a dialogue between the study participant and the PI occurred and is a comprehensive summary of the information shared. Further, the consent form is an important document-verifying enrollment into a study and thus must be on file in each participant's research record as appropriate.

Depending on the circumstance improperly completed and/or a missing consent form may exclude a participant from a study and data or samples may have to be discarded. Please note that the consent must be obtained in person, unless logistical circumstances require the consent be obtained by other means (e.g., telephone, mail, or fax).

First, some ground rules:
1)The consent form should be completed in ink, not pencil.

2) Make sure the most up-to-date version of the WRAMC approved consent form is used. The approved consent form is stamped by DCI and has the approval date and the protocol Work Unit # written in (see yellow highlighted area on the sample consent form). If a consent form is revised (e.g. based on an addendum or serious adverse event), it must be re-approved. The approved, revised consent form will be re-stamped by DCI, with updated dates written in the appropriate sections; previous versions of the consent form must not be used.

3) Surrogate Consent procedure must be approved by the HUC before it can be used. If a Surrogate Consent is being used to consent adults who are incapable of giving consent, the person acting as the surrogate must have legal authority to act on behalf of the patient. Such legal authority is evidenced by a power of attorney or court appointment as a guardian that authorizes the surrogate to approve participation in health care issues. It is not acceptable to ask the person who is accompanying a potential study subject, no matter what the relationship is, to provide consent without first establishing the legal authority of that person to act.

The following sections provide step-by-step instructions regarding the information to fill in on the consent form. These areas are highlighted in pink on the sample form.

Page 1:
Part A (1) VOLUNTEER AFFIDAVIT
If the study participant is an adult (age ≥ 18 years), they print:

1) their name on the line following "I,"
2) their SSN on the line following "SSN"
3) their age in years on the line following "having attained full capacity to consent and having attained my"
4) the word "myself" on the line following "do hereby volunteer/give consent as legal representative for"

If the study participant is a minor (age < 18 years), the parent or legal guardian prints the following in Part A(1):

(a) the name of the parent or legal guardian completing the consent form on the line following "I,"
(b) the SSN of the parent or legal guardian on the line following "SSN"
(c) the age in years of the parent or legal guardian on the line following "having attained full capacity to consent and having attained my"
(d) the name of the minor who will participate in the research on the line following "do hereby volunteer/give consent as legal representative for"

Page 2:
Part A (2) ASSENT VOLUNTEER AFFIDAVIT *(MINOR CHILD)*
If the study is approved only for adults, this section will be stamped "NOT APPLICABLE" by DCI and should be left blank.

If the study is open to minors, the minor may complete this section if they are of an age (usually >13 yrs) and have the cognitive capacity where assent is appropriate. For this section, the minor prints:

(a) their name on the line following "I,"
(b) their SSN on the line following "SSN"
(c) their age in years on the line following "having attained full capacity to consent and having attained my"
(d) the word "myself" on the line following "do hereby volunteer for"

"I Do/Do not consent to the inclusion of this form in my outpatient medical treatment record:" This box is now optional. If the patient wants to include the consent form in the outpatient medical record, the patient should check the "I Do" box. If neither box is checked, this will be interpreted to mean "Do not."

(Cont. on page 9)

Recently Approved Protocols at WRAMC

Congratulations to the following principal investigators on their recently approved protocols. The following protocols have been approved since last issue.

DENTAC

MAJ Daniel L. Trebus, DC	02-94000E: Prevalence of Soft Tissue Injuries with Use of Commercial Endotracheal Tube Holders

Department of Allergy-Immunology

CPT Mary M. Klote, MC	03-33004: Oropharyngeal Vaccinia Virus Presence After Smallpox Vaccination
LTC Michael R. Nelson, MC	03-33005: Immune Responses to Smallpox Vaccination

Department of Clinical Investigation

COL Maria H. Sjogren, MC	02-92012: Combination of Ribavirin with Interferon Alfacon-1 or with Pegylated Interferon Alfa 2b as Initial Treatment for Difficult to Treat Subjects Chronically Infected with Hepatitis C Virus

Department of Medicine

Cardiology Service

MAJ Daniel W. Isenbarger, MC	02-1200: Utility of the Pace-ECG for Diagnosis of Cardiac Hypertrophy
CPT Lance Sullenberger, MC	02-12008: The Accuracy of Physical Examination for the Diagnosis of Aortic Valvular Sclerosis
LTC Allen Taylor, MC	03-12003EX: Pharmacologic Interactions With Simvastatin In The National Capital Area Military Medical Treatment Facilities: Their Frequency And The Appropriateness Of Laboratory Monitoring

Endocrinology Service

COL Robert A. Vigersky, MC	02-13012: Continuous Glucose Monitoring in Patients with Type 2 Diabetes Mellitus

Gastroenterology Service

CPT Marten Duncan, MC	02-14013: Twenty-Four Hour pH Mntng and Histologic Evaluation in Patients with Tongues in the Distal Esophagus: Are These Findings Clinically Relevant?
Julia Friend, MPH, PA-C	03-14013EX: Treatment Outcomes In Hepatitis C: The Impact Of Dose Adjustments Secondary To Complications
CPT Marten Duncan, MC	03-14014EX: Do Accelerated Gastric Emptying Studies Have A Clinical Relevance? A Review Of Gastric Emptying Results, Indications, And Significant Symptoms From Referrals Within A Tertiary Care Center

Hematology-Oncology Service

CPT Jeremy G. Perkins, MC	02-15014: CALGB 19808: Phase III Randomized Study of Induction Chemotherpay With or Without MDR-Modulation with PSC-833 (NSC #648265, ind # 41121) Followed by Cytogenetic
COL Joseph J. Drabick, MC	02-15017: CALGB 40101/CTSU 40101: Cyclophosphamide and Doxorubicin (CA) (4 VS 6 Cycles) Versus Paclitaxel (12 Weeks vs 18 Weeks) as Adjuvant Therapy for Women with
COL Joseph J. Drabick, MC	02-15018: CALGB 30102: Phase III Comparison of Catheter Based Therapy of Pleural Effusions in Cancer Patients (Optimal Pleural Effusion Control, OPEC)
LTC Rickey C. Myhand, MC	02-16012: Phase II Randomized Trial of High-Dose Busulfan and Thiotepa 9BT) with Autologous Peripheral Blood Stem Cell (PBSC) Support Versus Standard Dose Docetaxel

(Cont. On page 8)

Recent WRAMC Publications

Congratulations to the following WRAMC investigators on their recently published papers. This list was compiled from a recent MEDLINE search of the literature. Listed articles have been cleared through DCI and the WRAMC Public Affairs Office. If you have recently published, and we have not included your publication, please let us know so we may list your publication in the next issue of the newsletter.

Byrd JC, Peterson BL, Morrison VA, Park K, Jacobson R, Hoke E, Vardiman JW, Rai K, Schiffer CA, Larson RA. **Randomized phase 2 study of fludarabine with concurrent versus sequential treatment with rituximab in symptomatic, untreated patients with B-cell chronic lymphocytic leukemia: results from Cancer and Leukemia Group B 9712 (CALGB 9712).** *Blood.* 2003 Jan 1;101(1):6-14.

Shawen SB, Belmont PJ Jr, Kuklo TR, Owens BD, Taylor KF, Kruse R, Polly DW Jr. **Hemimetameric segmental shift: a case series and review.** *Spine.* 2002 Dec 15;27(24):E539-44.

Schulze RA, Willard RJ, Turiansky GW. **Chronic palmar ulcer: a case of epithelioid sarcoma.** *Int J Dermatol. 2002* Dec;41(12):908-10.

Malone RD, Benedek DM, Carr RG. **Occupational psychiatry services in a military setting.** *Mil Med.* 2002 Dec;167(12):982-5.

Bucci JR, Matsumoto CS, Swanson SJ, Agodoa LY, Holtzmuller KC, Peters TG, Abbott KC. **Donor hepatitis C seropositivity: clinical correlates and effect on early graft and patient survival in adult cadaveric kidney transplantation**. *J Am Soc Nephrol.* 2002 Dec;13(12):2974-82.

Landau ME, Diaz MI, Barner KC, Campbell WW. **Changes in nerve conduction velocity across the elbow due to experimental error.** *Muscle Nerve*. 2002 Dec;26(6):838-40.

Abbott KC. **Excess cardiovascular mortality in chronic dialysis patients.** *Am J Kidney Dis.* 2002 Dec;40(6):1349-50.

Burch HB, Bernet VJ, Plotkin FR, McCord CF, Howard RS, Solomon BL, Magdycz WP, Craig SC. **Graves Disease in a US Army Special Forces Group.** *JAMA.* 2002 Dec 18;288(23):2975-6.

Miltner RS. **More than support: nursing interventions provided to women in labor.** *J Obstet Gynecol Neonatal Nurs.* 2002 Nov-Dec;31(6):753-61.

Trespalacios FC, Taylor AJ, Agodoa LY, Abbott KC. **Incident acute coronary syndromes in chronic dialysis patients in the United States.** *Kidney Int.* 2002 Nov;62(5):1799-805.

Bucci JR, Oglesby RJ, Agodoa LY, Abbott KC. **Hospitalizations for total hip arthroplasty after renal transplantation in the United States.** *Am J Transplant.* 2002 Nov;2(10):999-1004.

Taylor AJ. **Atherosclerosis imaging to detect and monitor cardiovascular risk.** *Am J Cardiol.* 2002 Nov 21;90(10 Suppl 3):L8-L11.

Dinauer P, Bojescul JA, Kaplan KJ, Litts C. **Bilateral lipoma arborescens of the bicipitoradial bursa.** *Skeletal Radiol.* 2002 Nov;31(11):661-5.

Viola RA, Abbott KC, Welch PG, McMillan RJ, Sheikh AM, Yuan CM. **A multidisciplinary program for achieving lipid goals in chronic hemodialysis patients.** *BMC Nephrol.* 2002 Nov 14;3(1):9.

Kaplan KJ, Burgess JR, Sandberg GD, Myers CP, Bigott TR, Greenspan RB. **Use of robotic telepathology for frozen-section diagnosis: a retrospective trial of a telepathology system for intraoperative consultation.** *Mod Pathol.* 2002 Nov;15(11):1197-204.

Taylor JA 3rd, Gancarczyk KJ, Fant GV, Mcleod DG. **Increasing the number of core samples taken at prostate needle biopsy enhances the detection of clinically significant prostate cancer.** *Urology.* 2002 Nov;60(5):841-5.

Bauer AJ, Terrell R, Doniparthi NK, Patel A, Tuttle RM, Saji M, Ringel MD, Francis GL. **Vascular endothelial growth factor monoclonal antibody inhibits growth of anaplastic thyroid cancer xenografts in nude mice.** *Thyroid.* 2002 Nov;12(11):953-61.

Machen MS, Tis JE, Inoue N, Meffert RH, Chao EY, McHale KA. **The effect of low intensity pulsed ultrasound on regenerate bone in a less-than-rigid biomechanical environment.** *Biomed Mater Eng.* 2002;12(3):239-47.

Abbott KC, Bakris GL. **Treatment of the diabetic patient: focus on cardiovascular and renal risk reduction.** *Prog Brain Res.* 2002;139:289-98.

Jackson JL, O'Malley PG, Salerno SM, Kroenke K. **The teacher and learner interactive assessment system (TeLIAS): a new tool to assess teaching behaviors in the ambulatory setting.** *Teach Learn Med.* 2002 Fall;14(4):249-56.

Bernet VJ, Anderson J, Vaishnav Y, Solomon B, Adair CF, Saji M, Burman KD, Burch HB, Ringel MD. **Determination of galectin-3 messenger ribonucleic Acid overexpression in papillary thyroid cancer by quantitative reverse transcription-polymerase chain reaction.** *J Clin Endocrinol Metab.* 2002 Oct;87(10):4792-6.

(Cont. on page 7)

Departure of the Principal Investigator (PI) from an Ongoing Research Protocol

As the principal investigator (PI) of an ongoing WRAMC research protocol what happens if I leave WRAMC (i.e., transfer of duty station or retiring)? Do I need to inform DCI? Can I take all the study files and consent forms with me? These are concerns and questions that many PIs have in regard to departing WRAMC.

If you are the PI on an ongoing research study and leaving WRAMC, either a new principal investigator needs to be designated to continue the study or steps must be taken to close (or end) the study. Whichever decision you make, please remember to complete this prior to your departure from WRAMC!

Designating a New PI: To designate a new PI, the current PI submits a request form including required supporting documents found under filename "PI-Change.doc" on the DCI website. The new PI needs to sign this document, which includes the 'Responsibilities of PI Statement' and 'Investigator Compliance Memorandum'. The new PI must be assigned/employed at WRAMC. The request form and an original updated consent form, if applicable, are submitted to the DCI protocol coordinator, Research Review Service.

DCI will confirm the designation of the new PI with a written memo to the current and new PI. If applicable, the updated consent form will be stamped by DCI and returned to the PI to use for enrollment of subsequent research subjects. The PI change will be reported to the HUC and a copy of the HUC minutes will be forwarded to the PI and should be placed in the Protocol Administrative Binder.

During the transition, the current PI needs to transfer all research records and administrative documents of the research study to the new PI. Research records are the property of WRAMC, not the investigator. Investigators are not allowed to take study records with them when they depart.

Closing a Study: To close the study, an Annual Progress Report (APR) must be submitted, requesting closure of the study. See the DCI website for instructions and template.

Please remember that it is very important for PIs to close their study or provide a change of PI if they depart WRAMC. Studies for which this is not done will be administratively terminated and data from terminated studies may not be published.

For questions in regard to changing the PI on an ongoing study or closing a study, please contact Verna Parchment at (202) 782-7828 or Verna.Parchment@na.amedd.army.mil.

Recent WRAMC publications (cont from page 6)

Winter WE 3rd, Kucera PR, Rodgers W, McBroom JW, Olsen C, Maxwell GL. **Surgical staging in patients with ovarian tumors of low malignant potential.** *Obstet Gynecol. 2002 Oct;100(4):671-6.*

Abbott KC, Bucci JR, Cruess D, Taylor AJ, Agodoa LY. **Graft loss and acute coronary syndromes after renal transplantation in the United States.** *J Am Soc Nephrol. 2002 Oct;13(10):2560-9.*

Fishbain JT, Viscount HB. **Surveillance for methicillin-resistant Staphylococcus aureus in Battambang, Cambodia.** *Hawaii Med J. 2002 Oct;61(10):231-2.*

Tis JE, Klemme WR, Kirk KL, Murphy KP, Cunningham B. **Braided hamstring tendons for reconstruction of the anterior cruciate ligament. A biomechanical analysis.** *Am J Sports Med. 2002 Sep-Oct;30(5):684-8.*

Black N, Morris J. **The child and adolescent psychiatrist in the Pentagon response.** *Mil Med. 2002 Sep;167(9 Suppl):79-80.*

Huleatt WJ, LaDue L, Leskin GA, Ruzek J, Gusman F. **Pentagon Family Assistance Center inter-agency mental health collaboration and response.** *Mil Med.* 2002 Sep;167(9 Suppl):68-70.

Waldrep D, Waits W. **Returning to the Pentagon: the use of mass desensitization following the September 11, 2001 attack.** *Mil Med.* 2002 Sep;167(9 Suppl):58-9.

Milliken CS, Leavitt WT, Murdock P, Orman DT, Ritchie EC, Hoge CW. **Principles guiding implementation of the Operation Solace plan: "Pieces of PIES," therapy by walking around, and care management.** *Mil Med.* 2002 Sep;167(9 Suppl):48-57.

Waits W, Waldrep D. **Application of Army Combat Stress Control doctrine in work with Pentagon survivors.** *Mil Med.* 2002 Sep;167(9 Suppl):39-43.

Wain HJ, Grammer GG, Stasinos JJ, Miller CM. **Meeting the patients where they are: consultation-liaison response to trauma victims of the Pentagon attack**.*Mil Med.* 2002 Sep;167(9 Suppl):19-21.

Cozza SJ, Huleatt WJ, James LC. **Walter Reed Army Medical Center's mental health response to the Pentagon attack.** *Mil Med.* 2002 Sep;167(9 Suppl):12-6.

Recently Approved Protocols at WRAMC (cont. from page 5)

MAJ Jamie K. Waselenko, MC	02-16013: A Phase II Clinical Trial of BMS-247550 (NSC #710428), An Epothiline B Analog in Patients with Breast Carcinoma
COL Joseph J. Drabick, MC	03-15020: CALGB 49907: A Randomized Trial of Adjuvant Chemotherapy with Standard Regimes, Cyclophosphamide, Methotrexate and Fluorouracil - (CMF) or Doxorubicin and
COL Joseph J. Drabick, MC	03-15023: CALGB 80003: A Phase II Study of Gemcitabine, 5-Fluorouracil and Radiation Therapy in Locally Advanced Non-Metastatic Pancreatic Adenocarcinoma

Infectious Disease

CPT Timothy Straight, MC	03-19003EX: Morbidity And Mortality Associated With *Staphylococcus Aureus* Bacteremia At A Tertiary Care Center

Pulmonary & Critical Care Medicine Service

MAJ Scott J. Johnson, MC	02-17012: Perioperative Beta-Blockade in Patients with Chronic Obstructive Pulmonary Disease
CPT Bruce Greenberg, MC	02-17021E: Thalidomide Induced Acute Renal Failure: A Case Report and Review of the Literature.
CPT Christopher Lettieri, MC	03-17021EX: Predictors of Outcomes for Surgical Lung Biopsy in Patients with Interstitial Lung Disease

Department of Neurology

MAJ John Y. Choi, MC	02-71007: A Pilot Study Using Actigraphy to Assess Functional Severity and Recovery of Motor Limbs in Acute Brain Injury
LTC William Campbell, MC	02-71008: Modafinil in the Treatment of Fatigue in Post-Polio Syndrome
Deborah L. Warden, M.D.	02-71009: A Randomized Placebo-Controlled Trial of Sertraline for Chronic Neurobehavioral Sequelae of Traumatic Brain Injury
Deborah L. Warden, M.D.	02-71011: Enhanced Head Protection for Paratroppers: Efficacy of Countermeasures Against Traumatic Brain Injuries Sustained in Airbone Operations
LTC Mark Landau, MC	03-71005EX: Changes In Nerve Conduction Velocity Across The Elbow Due To Experimental Error

Department of Nursing

COL George F. Nussbaum, AN	02-75014: Do Culturally Acquired Behavior Norms Impact Workplace Communication?
LTC Elmer W. Combs, AN	02-75018: Musculoskeeletal Injury in Amedd Soliders
CPT Anthony Peverini, AN	02-75019: Gender Differences in Propofol Dosage During Regional Anesthesia

Department of Obstetrics and Gynecology

LTC Scott G. Rose, MC	02-43009: GOG #0185: A Phase III Randomized Study of Adjuvant Radiation Treatment Versus Radiation and Chemotherapy in Patients with Vulvar Cancer and Involved Nodes

(Cont on page 10)

Step-By-Step Guide for Consenting Subjects (cont p. 4)

Volunteer Signature Blanks:

(a) SIGNATURE OF VOLUNTEER is completed by the consenting adult or assenting minor who will be participating in the research. *This block should be initialed on subsequent pages.*

(b) DATE is completed by the consenting adult or parent/legal guardian. *Every page (from page 2 on) must be dated.*

(c) SIGNATURE OF LEGAL GUARDIAN (If volunteer is a minor) is signed by the parent or legal guardian who consents to include their legal minor in the research; this block may be initialed on subsequent pages.

(d) PERMANENT ADDRESS OF VOLUNTEER is printed on page 2 by the consenting adult or parent/legal guardian; this block may be left blank on subsequent pages.

Witness Signature Blanks:

Signature witnesses generally are not required, unless specifically required by the Walter Reed HUC. If a signature witness is required, complete the blanks as follows:

a) TYPED NAME OF WITNESS is typed or printed on page 2 by someone who has witnessed the volunteer or parent/legal guardian sign the consent form. The purpose of the witness is to confirm the authenticity of the signature, not to confirm the volunteer's or the parent's/legal guardian's understanding of the research. The witness may be a member of the study team other than the principal investigator, a member the clinic staff, a family member, or friend of the research participant. The witness name must be printed on page 2, but on subsequent pages this item may be left blank.

b) SIGNATURE OF WITNESS and DATE are completed by the witness on page 2; this block may be left blank on subsequent pages.

Medical Research Alert: NEED TO CLEARLY INDICATE DATE ON PROTOCOL REVISIONS

Three months ago, we sent out a Research Alert requesting that you submit new protocols electronically.

We very much appreciate your cooperation, and I'm happy to report that we are now receiving electronic versions for over 90% of all protocols. This really helps the entire review process.

However, we are still having some difficulty in one area: Principal Investigators inadvertently making their changes into a prior version of the protocol or consent form.

Then the two versions of the document need to be reviewed on a line-by-line basis -- this is a very time-consuming process.

When updating your protocol, **be sure to indicate the current date of your protocol** in two places:

1. In the file name (what you see when you look at the icon on the computer monitor), and
2. In the Header of the actual protocol or consent form document.

Here's how to do it:

1.File Name:

We request your file name indicate the date of the most recent revision, your last name (or other unique identifier, eg, CALGB 90010), and what's in the document (Protocol, consent form, etc.). Here are 3 examples:

a. 12-5-02.Smith.Prot.doc
b. 12-11-02.Z0070.CF.doc
c. 12-16-02.CALGB90010.Impact.doc

2. Document Header:

When you type your protocol in MS Word, go to View, then Header and Footer. Then click the Insert Date command.

These 2 steps are very simple, and will save all of us a lot of time.

Thank you, and do not hesitate to contact me if you have any questions or comments.

Edward E. Bartlett, PhD
IRB Administrator

Recently Approved Protocols at WRAMC (cont. from page 8)

LT Adrienne B. Neithardt, MC	03-44009: Procurement of Follicular Fluid for Studies of Granulosa Cell Function
Department of Orthopaedics and Rehabilitation	
LTC Kevin P. Murphy, MC	02-24018: Anterior Cruciate Liagment Reconstructino with Fracilis and Semitendinosus Tendons: Comparison Between Patients Over 40 Years of Age Versus Those Les Than 40
LTC Martha Lenhart, MC	02-24019: Use of Telemedicine in Optimizing Care for Phalangeal Fractures
CPT Patrick J. Pollock, MC	03-24022: Measurement of Distal Lower Extremity Tibiofibular Syndesmosis; Evalaution of Validity and Intraobserver and Interobserver Variability
CPT Mary C. Hannah, SP	02-96006: New Plantar Fasciitis Orthotic (PFOs) Versus Traditional Conservative Treatment for Plantar Fasciitis: A Randomized Controlled Trial
CPT Matthew Walsworth, MC	03-96007: Diagnostic Accuracy of Shoulder Exam Tests
LTC Gerald Farber, MC	02-24023E: Revision Of Ulnar Nerve Transpositions; A Retrospective Review
CPT Michael DeMarco, MC	03-96011EX A Retrospective Analysis of Patient Referrals to the Physical Medicine Service at Walter Reed Army Medical Center During Operation Enduring Freedom
CPT David Jensen, MC	03-96012EX Epidemiological Analysis Of Injuries From Army Ten Miler, A Four Year Retrospective Review
Department of Pathology	
LTC Aizen J. Marrogi, MC	02-48005: Oxidative and Nitrosative Stress in Carcinogenesis of CTCL in Archived Tissue Samples from Patients Diagnosed with Mycosis Fungoides (MF)
CPT Timothy Dickason, MC	03-48003EX: Correlation Between WHO Grade And Percent Carcinoma In Prostate Biopsy Specimens With Extraprostatic Extension In The Radical Prostatectomy Specimen
Department of Pediatrics	
LTC Thomas R. Burklow, MC	02-65008N: Clinical Use of the Amplatzer PFO Occluder
Department of Psychology	
MAJ Debra Dunivin, MS	02-73004: The Impact of Group Psychosocial Interventions on Quality of Life for Breast Cancer Patients and Their Partners: A Pilot Study
Department of Radiology	
MAJ Robert S. Bridwell, MC	02-45005: What is the Sensitivity of Tc-99m Apcitide to Detect Acute Pulmonary Emboli?
MAJ Robert S. Bridwell, MC	02-45006: IM-D-MN3-22: Phase II Study of LeukoScan Imaging in Patients with Acute Anthrax Infections
MAJ John J. O'Connell, MC	03-46001EX: Confirmation Of Daily Patient Position Reproducibility During Stereotactic Radiotherapy
MAJ John D. Statler, MC	03-47009EX: Plain Film Urography: Quality Assessment

(Cont on page 13)

Clinical Research Meetings & Conferences

Below is a list of meetings and conferences focusing on various aspects of clinical research. For more information, please see the specific website:

27 January: HIPAA Fundamentals for Human Research Protection Programs. This conference is held in Washington, DC and will provide an overview of the Privacy Rule with specific attention to the impact on research and what the covered entity/IRB must do to be in compliance with the Rule. Specific topics will include: background and history of HIPAA, key concepts for successful HIPAA compliance, identifiability, individual rights, limited data sets, authorization and how it relates to informed consent, waiver of authorization, new subject's rights provided by the Rule, and specific concerns for IRBs. www.primr.org/hipaa.htm

20-22 February: The Future Face of IBCs: Evolving Roles and Responsibilities, Upcoming Challenges and Opportunities. This conference will be held in San Diego, CA. The main conference will take place February 21-22 and is intended for Institutional Biosafety Committee (IBC) members and staff and others who have an interest in the oversight of recombinant DNA research. A major purpose of this event is to promote the professional development of those associated with IBCs. A special training session for new IBC members and staff will be held on February 20. www.capconcorp.com/ibc2003/

24-25 February: International Issues: Human Subjects Protections. This workshop will be held in San Juan, Puerto Rico and is sponsored by the Office for Human Research Protections (OHRP) and is hosted by the Inter American University and the University of Puerto Rico. This workshop will focus on responsibilities of researchers, Institutional Review Boards (IRBs), and institutional officials for the protection of human subjects in research. The workshops are open to everyone with an interest in research involving human subjects. The meetings should be of special interest to those persons currently serving or about to begin serving as a member of an IRB. ohrp.osophs.dhhs.gov/wrkshp.htm

29 March-1 April: Institutional Animal Care and Use Committees (IACUC) Annual Conference. This conference will be held in San Diego, CA and is sponsored by PRIM&R and ARENA. Discussions will include: new developments in operational areas; grant proposal/IACUC protocols; priority concerns for IACUCs around the country; policy and practice developments related to approved protocols; and effective mechanisms for monitoring the post-approval conduct of research www.primr.org/iacuc1202.htm

Research Alert List Reminder!

In order to provide better service to Walter Reed researchers, DCI has established a Researcher Alert List.

The Researcher Alert List consist of important periodic updates on policy changes, procedures, regulations, etc. that directly impact Walter Reed medical researchers.

For example, DCI has been receiving a record number of new protocols in the past two months, and has made a number of changes to assure these protocols are reviewed in a timely manner. We will be announcing these changes on the Researcher Alert List shortly.

If you are a Principal Investigator, Associate Investigator, research nurse, or want to be kept informed of key research developments, it is important that you be included on this list.

In order to receive the Research Alerts, e-mail Ms. Marty Green at (202) 782-7864 or Marty.Green@na.amedd.army.mil, and request to be added to the Research Alert list.

Upcoming Presentations on the Effects of HIPAA on Research

The Health Insurance Portability and Accountability Act of 1996 includes patient privacy regulations that go into effect on 14 April 2003. HIPAA, also known as *"The Privacy Rule"*, specifically defines confidentiality as it pertains to research. Although the provisions of this law and their application to research are beyond the scope of this notice, suffice it to say that *the law will affect the way researchers access, manage, and disclose patient's health information.*

Although Army guidance on numerous issues pertaining to the law is pending, DCI wants to raise the awareness of researchers about the law. To this end, three 1 hour lectures on HIPAA as it pertains to research have been scheduled for 12 & 26 February as well as 12 March beginning at 0730 in room 2H26, Bldg 2. WRAMC researchers are highly encouraged to attend one of these lectures.

Research In Clinical Medicine: Basic Concepts Approach Registration Available mid-January 2003!

The Department of Clinical Investigation is proud to announce the "Research In Clinical Medicine: Basic Concepts Approach" course for military and civilian clinical researchers (and aspiring researchers) at Walter Reed Army Medical Center.

This is a three-part series of workshops that provides clinical investigators with the opportunity to learn and apply the principles of good research design in the development of a research proposal. The content of each session is as follows:

Session 1. Ethical studies, the Logic of Research, Science of Medicine
Session 2. Study Design and Critical Appraisal of the Literature
Session 3. Principles of Statistics for Clinical Investigators (a basic concepts approach)

The course is limited to 25 participants and is free of charge to WRAMC personnel. Each participant will receive a course notebook with presentation and workshop notes, pertinent handouts and articles, and a certificate of completion.

The course will meet on 3 consecutive Thursday afternoons in May (15, 22, & 29 May) from 1300-1600 in Bldg 6 (Borden Pavilion), 4th floor, DCI conference room.

Registration will be available on the DCI website (www.wramc.amedd.army.mil/departments/dci) in mid-January 2003. For further information, please contact LTC Raul Marin at (202)782-7840 or at Raul.Marin@na.amedd.army.mil.

USUHS Schedules Annual Research Day for 14-15 May

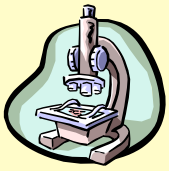
The Uniformed Services University of the Health Sciences (USUHS) has scheduled the 10th annual Faculty Senate Research Day & Graduate Student Colloquium for 14 and 15 May 2003. This year's theme has not been decided.

Research Day is held to promote basic science and clinical research collaboration among investigators at USUHS, WRAMC, the National Naval Medical Center, the Naval Medical Research Center, WRAIR, the Armed Forces Radiobiology Research Institute, the Henry M. Jackson Foundation for the Advancement of Military Medicine and other affiliated institutions.

The event seeks to promote research career enhancement and to educate the researcher in such topics as animal use, grants administration, new methodologies, ethics, patent issues, and radiation & lab safety. Research Day also aims to encourage student awareness and involvement in research activities.

The two day event will include invited lectures addressing this year's theme, workshops, and oral & poster presentations by USUHS graduate students and other affiliated institutions. The deadline to submit abstracts for presentations will be announced at a later date.

Please see the website www.usuhs.mil/resday/rd2003.html for future updates.



IRB Calendar

The following Institutional Review Board (IRB) meetings will be held in the months of January, February and March 2003:

CLINICAL INVESTIGATION COMMITTEE (CIC):

07 January	04 February	04 March
21 January	18 February	18 March

HUMAN USE COMMITTEE (HUC):

14 January	11 February	11 March
28 January	25 February	25 March

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC):
13 March

All meetings will begin at 1300, except HUC meetings which will start at 1200. All meetings will be held in the fourth floor conference room, Building 6, WRAMC.

"Investigator 101" CD-ROM Now Available

The **Investigator 101 CD-ROM** was produced by the Public Responsibility in Medicine and Research (PRIM&R) organization and provides education on the responsible conduct of human research and protection of human subjects. The course contains two presentations, Part 1: "The History and Ethics of Human Subject Research", with Dr. Jeffrey Cooper (Chair, IRB Albany Medical Center), and Part 2: "The Top 10 Responsibilities of Investigators", with Ms. Ada Sue Selwitz (Office of Research Integrity, University of Kentucky). Both talks are divided into short modules. Written transcripts of the talks and a comprehensive set of hyper-linked references and reading materials are also available. For more information on the CD-Rom see: www.primr.org/101cdrom.html.

Copies of the CD-ROM are available to WRAMC researchers at no charge. For your free copy, please call DCI at 202-782-6389.

Recently Approved Protocols at WRAMC (cont. from page 10)

Department of Surgery

Army Audiology & Speech Center

COL David W. Chandler, MC	02-25006: Reliability and Validty of Otoacoustic-Emission (OAE) Paradigms
Kenneth W. Grant, Ph.D.	02-25008: Discrmination of Temporal Asynchrony Within and Across Sensory Modalities

General Surgery Service

MAJ Cletus Arciero, MC	03-20006EX: Intraoperative Turbo Parathyroid Hormone Assessment In Patients Undergoing Total Parathyroidectomy For Primary Hyperparathyroism

Plastic Surgery Service

COL Daniel S. Jorgenson, MC	02-29002: Mentor Adjunctive Study for Silicone Gel-Filled Mammary Prostheses

Urology Service

COL David G. McLeod, MC	02-28009: An Open-Label, Multi-Center, Ascending, Single Dose Study Investigating the Pharmacokinetics, Pharmacodynamics and Safety of FE200486 in Prostate Cancer Patients
COL David G. McLeod, MC	02-28010: An Open-Label, Multi-Center, Extension Study Investigating the long-Term Safety and Tolerability of Repeat Doses of FE200486 in Prostate Cancer Patients - Protocol FE200486
COL David G. McLeod, MC	02-28011: An Open-Label Trial on the Effect of I.V. Zometa 4 mg on Bone Mineral Density in Hormone Sensitive Prostate Cancer Patietns with Bone Metastasis
COL Judd W. Moul, MC	02-2857-98j: Prostate Cancer Lifestyle Trial and CPDR Database Comparison
CPT Stacey Koff, MC	03-28007EX: Water Induced Thermotherapy for the Treatment of Benign Prostatic Hyperplasia and Urinary Retention

Inquiring Minds is published quarterly by the Department of Clinical Investigation, WRAMC, as a service to DCI employees and the WRAMC research community.

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Any submissions or questions about content should be directed to CPT Ken Capps at (202) 782-7823.